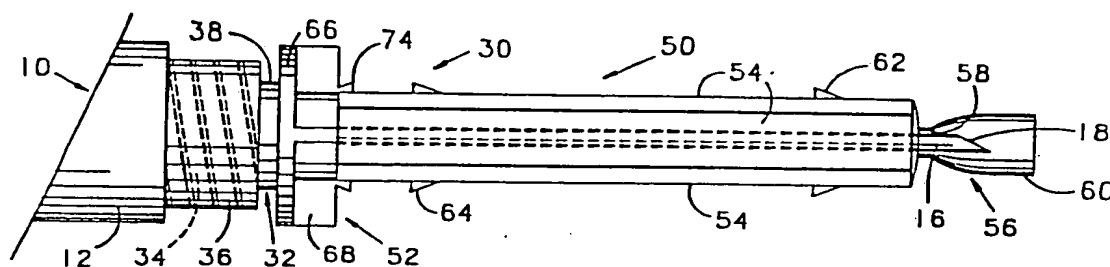




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<b>(21) International Application Number:</b> PCT/US93/02079 <b>(22) International Filing Date:</b> 8 March 1993 (08.03.93) <b>(30) Priority data:</b> 850,379 10 March 1992 (10.03.92) US <b>(71) Applicant:</b> INJECTIMED, INC. [US/US]; 2737 Palma Drive, Ventura, CA 93003 (US). <b>(72) Inventors:</b> KURACINA, Thomas, C. ; 329 Gridley Road, Ojai, CA 93023 (US). OHNEMUS, Randall, E. ; 1794 San Gabriel Avenue, Ventura, CA 93003 (US). SMITH, Craig, W. ; 2737 Palma Drive, Ventura, CA 93003 (US). <b>(74) Agents:</b> DAVIS, Anthony, G., M. et al.; Davis, Bujold & Streck, 175 Canal Street, Manchester, NH 03101 (US).		<b>(81) Designated States:</b> AU, BR, CA, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>

**(54) Title:** MEDICAL INJECTION DEVICES WITH SAFETY FEATURES**(57) Abstract**

Improvements to a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying the needle and an outer end covering the needle's tip. There is a releasable base attaching to a device such as a syringe. The base supports a hard cover used to attach and release the needle and sleeve. A bell-end provides a point of sliding on the needle behind the tip and viewing of the tip when transparent. The tip is placed in a pre-established orientation and the sleeve is marked so that the needle can be positioned before the sleeve is retracted. Where a spring-biased collar is used over the sleeve, the base has gripping tabs to hold the spring, the collar has an extended area for sliding stacking of the spring upon retraction, and another extended area for protecting the front holding projections when the sleeve is extended. A dental version has the slats at the rear to fold outward outside the patient's mouth. By reversing the front projections, the sleeve locks up after one use. A strongback adjacent the front end of the sleeve helps in creating a repeatable folding pattern. A gripping ring aids in manually retracting the sleeve. Living hinges also help in creating a repeatable folding pattern. The living hinges may include indentations representing an identification number.

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## MEDICAL INJECTION DEVICES WITH SAFETY FEATURES

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### BACKGROUND OF THE INVENTION:

This invention relates to medical devices for injecting living bodies and, more particularly, to safety features  
10 incorporated therewith. In particular, it relates to improvements to retractable sleeves for protecting hypodermic needles and the like.

In United States Patent No. 4,998,922 by Thomas C. Kuracina entitled SAFETY SYRINGE CAP MINIMIZING  
15 NEEDLE-STICK PROBABILITY which issued 12 March 1991, a safety device for hypodermic needles and the like is shown. The inventions shown hereinafter are improvements thereto by inventors including and/or working with Mr. Kuracina. In the interest of simplicity herein, the teachings of that patent are  
20 incorporated herein by reference and the discussion of the background art will be kept to a minimum.

A typical prior art hypodermic syringe 10 as shown in Figure 1 includes a barrel 12 having a moving plunger 14 therein. A needle 16 having a sharp beveled tip 18 extends from  
25 the end opposite the end of the barrel 12 into which the plunger 14 is inserted. The needle 16 is covered by a removeable cap 20 for safety purposes. The problem to be solved and avoided is the accidental sticking of users of the syringe 10 by the tip 18 after use where the tip 18 may carry body fluids containing  
30 agents of hepatitis B, AIDS, and the like. Accidental needle stick is a very common problem in the health care industry and besides the risk of serious illness or even death as a result thereof, the insurance industry spends over a billion dollars a year in the testing of individuals who have been subjected to  
35 post-use needle stick.

The 1979 patent of Alvarez proposed a retractable plastic protective sleeve 22 as depicted in Figures 2 and 3. The Alvarez sleeve 22 has an inner hub 24 which fits around the base of the needle 16 and an outer hub 26 through which the tip 18 passes.

5 The inner and outer hubs 24, 26 are connected by curved slats 28. When the needle 16 is to be inserted into the body of a patient, the force required to move the sleeve 22 from its extended position of Figure 2 to its retracted position of Figure 3 is as depicted in the graph of Figure 4. Thus, there is really no

10 actually safety from a large variety of ways in which accidental needle stick takes place. Even if the sleeve 22 fully extends after use, a slight blow against a user or observer in the area will cause the sleeve 22 to retract and the tip 18 to stick the unfortunate person.

15 The action of the basic protective sleeve of the above-referenced Kuracina patent is depicted in Figure 5. A high degree of force is required to move the protective sleeve from its extended position covering the tip 18. Moreover, a spring-biased locking collar is added over the protective sleeve which

20 all but prevents the protective sleeve from moving from its extended position covering the tip 18. The collar must be moved from its locked position to a retracted, unlocked position before the deformation qualities of the sleeve depicted in Figure 5 take effect. After use, the locking collar springs back to its

25 locked position. Thus, in virtually all "accidental" contact with the tip end of a hypodermic syringe, actual penetration by the tip 18 should be prevented.

The inventions described hereinafter are intended to make the Kuracina protective sleeve even safer and more easy to use

30 while also adapting it to various mounting configurations.

Other objects and benefits of the inventions disclosed herein will become apparent from the detailed description which follows hereinafter when taken in conjunction with the drawing figures which accompany it.

## SUMMARY:

The foregoing object has been achieved in a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle by the following improvements:

The outer end being bell-shaped with a point of sliding contact on the hypodermic needle located behind the injection end.

The bell-shaped outer end of the hypodermic needle being transparent whereby the injection end of the hypodermic needle can be visually inspected through the bell-shaped outer end.

A projection extending from the medical device; and, attachment means included with the base for releasably attaching the hypodermic needle in combination with the retractable sleeve to the projection. The projection being a cylindrical projection having a cylindrical bore therein; and, the attachment means comprising a cylindrical member sized and shaped to slidably fit within the cylindrical bore. The cylindrical bore having internal threads formed therein; and, the cylindrical member having external projections which threadedly engage the internal threads whereby the cylindrical member is threaded into the cylindrical bore to releasably attach the hypodermic needle in combination with the retractable sleeve to the projection.

The base including radial longitudinal gripping vanes; and additionally comprising, a hard cover disposed over the retractable sleeve and supported by the vanes, the hard cover having interacting means on an inner surface thereof for radially pushing the vanes to release the attachment means from the projection when the hard cover is rotated whereby the hard cover can be used to attach the hypodermic needle and the

retractable sleeve in combination therewith to the projection and release the hypodermic needle and the retractable sleeve in combination therewith from the projection.

A projection extending from the medical device; and,  
5 attachment means included with the base for releasably attaching the hypodermic needle in combination with the retractable sleeve to the projection; wherein, the base comprises a first part carrying the bottom end of the hypodermic needle and a second part carrying bottom ends of the plurality of  
10 longitudinal slats; and additionally, the base includes means for placing the injection end of the hypodermic needle in a pre-determined positional orientation with respect to the retractable sleeve. The means for placing the injection end of the hypodermic needle in a pre-determined positional orientation  
15 with respect to the retractable sleeve may comprise the first part and the second part being parts of a unitary structure comprising the base with the injection end of the hypodermic needle carried thereby in the pre-determined positional orientation with respect to the retractable sleeve. The means  
20 for placing the injection end of the hypodermic needle in a pre-determined positional orientation with respect to the retractable sleeve may also comprise mating portions of the first part and the second part which only mate when the injection end of the hypodermic needle is in the pre-determined positional  
25 orientation with respect to the retractable sleeve. Also, indicia means carried by the retractable sleeve indicate to a user the pre-determined positional orientation of the injection end of the hypodermic needle with respect to the retractable sleeve whereby a user can place the injection end of the hypodermic  
30 needle in a desired positional orientation before retracting the retractable sleeve.

When a sliding collar and bias spring are disposed over the retractable sleeve with the spring disposed between the base and the sliding collar to bias the sliding collar towards the outer

end, gripping tabs are carried by the base for gripping and holding a base end of the spring.

Where the slats have front and rear projections extending therefrom to prevent the sliding collar from sliding off the outer end and to releasably latch the sliding collar in a retracted position for use, the preferred projections are triangles in shape having a vertical side adjacent the base and a sloped side facing the outer end. The preferred sliding collar has an extended inner cylindrical portion which fits under a plurality of turns of the spring when the sliding collar is moved to a retracted position behind rear ones of the projections. The preferred sliding collar also has an extended outer cylindrical portion which covers and protects front ones of the projections from unwanted depression and release of the sliding collar when the sliding collar is in an extended position held by the front ones of the projections.

For dental use and the like, the plurality of longitudinal slots are located longitudinally offset more adjacent the base than the outer end whereby the plurality of longitudinal folding slats fold adjacent the base and an extended portion of the retractable sleeve adjacent an exposed injection end of the hypodermic needle is not deformed outward during retraction of the outer end and all outward movement of the slats takes place outside of the patient's mouth.

To make the hypodermic needle usable only once, the projections are triangles in shape with rear ones of the projections having a vertical side adjacent the base and a sloped side facing the outer end and front ones of the projections having a sloped side adjacent the base and a vertical side facing the outer end; and, there are retaining ridge means for not allowing the sliding collar to pass thereover disposed adjacent the outer end and past the front ones of the projections towards the outer end whereby the locking collar when released from a retracted position held by the rear ones of the projections is

moved over the front ones of the projections by a biasing force of the spring and locked between the front ones of the projections and the retaining ridge means.

For added reliability and consistency of operation, there  
5 may be thickened strongback areas in the plurality of longitudinal slats extending from respective ones of the front projections toward the base. Also, respective ones of the plurality of longitudinal slats may transverse areas forming living hinges at corresponding locations of intended bending

10 For increasing the ease of manual retraction of the retractable sleeve, there may be a gripping area extending radially outward from the outer end, the gripping area having a high friction surface whereby a user can reliably grip and pull the outer end longitudinally toward the base even when the  
15 outer end is covered with slippery fluid.

The living hinges can be created in part by a plurality of indentations disposed in an outer surface of at least one of the plurality of longitudinal slats, the plurality of indentations being in a pattern representing an identification number of the  
20 retractable sleeve and hypodermic needle in combination.

#### DESCRIPTION OF THE DRAWINGS:

Figure 1 is a simplified, partially cutaway drawing of a prior art hypodermic syringe with a removeable protective cap.

25 Figure 2 is a simplified, partially cutaway drawing of the front portion of a hypodermic syringe with a prior art retractable protective sleeve over the needle thereof in its extended position.

Figure 3 is a simplified, partially cutaway drawing of the  
30 front portion of a hypodermic syringe with a prior art retractable protective sleeve over the needle thereof as in Figure 2 with the sleeve in its retracted position.

Figure 4 is a graph showing the force required to move the protective sleeve of Figure 2 to the position of Figure 3.



Figure 5 is a graph showing the force required to move a protective sleeve according to one of the inventors hereof from its extended position to its retracted position.

Figure 6 is a simplified, partially cutaway drawing of the front portion of a hypodermic syringe with a retractable protective sleeve over the needle thereof depicting certain improvements according to the present invention.

Figure 7 is a partially cutaway drawing of the apparatus of Figure 6.

Figure 8 is a partially cutaway drawing of the hub portion of the apparatus of Figures 6 and 7.

Figure 9 is a cutaway drawing through the cap-carrying collar of the apparatus of Figures 6-8.

Figure 10 is an exploded view of the cap-carrying collar of the apparatus of Figures 6-8 and the needle-carrying inner hub in an aligned configuration.

Figure 11 is an end view of the needle-carrying inner hub.

Figure 12 is a cutaway end view of the needle-carrying inner hub.

Figure 13 is a simplified, partially cutaway drawing of the front portion of a hypodermic syringe with a retractable protective sleeve over the needle thereof and the spring-biased locking collar disposed over the sleeve depicting certain additional improvements according to the present invention.

Figure 14 is an exploded, partially cutaway view of the cap-carrying collar and the needle-carrying inner hub in an unaligned configuration.

Figure 15 is a partially cutaway view of the cap-carrying collar and the needle-carrying inner hub of Figure 14 as assembled.

Figure 16 is a partially cutaway view of the apparatus of Figure 13 with the addition of a preferred protective cap.

Figure 17 is a simplified drawing of the front portion of a hypodermic syringe with a retractable protective sleeve over the

needle thereof according to the present invention in an embodiment intended for dental use and the like.

Figure 18 is a simplified, partially cutaway drawing of the front portion of a hypodermic syringe with a retractable protective sleeve of Figure 17 over the needle thereof in its retracted position.

Figure 19 is a simplified, cutaway drawing of the front portion of a hypodermic syringe with a retractable protective sleeve over the needle thereof wherein the needle has the bevel tip thereof in alignment with an indicator on the sleeve end.

Figure 20 is an end view of Figure 19.

Figure 21 is a simplified, partially cutaway drawing of the front portion of a hypodermic syringe with a retractable protective sleeve over the needle thereof according to the present invention in an embodiment wherein the spring-biased locking collar is shipped in a retracted position and moves to an extended and locked position when used.

Figure 22 is a simplified, partially cutaway drawing of the front portion of a hypodermic syringe with a retractable protective sleeve over the needle thereof according to the present invention in an embodiment which includes a strongback to help in collapsing of the sleeve in a pre-determined manner and a gripping portion at the front of the sleeve to aid in the manual retract thereof when necessary.

Figure 23 is a simplified drawing of the front portion of a hypodermic syringe with a retractable protective sleeve over the needle thereof according to the present invention wherein there are living hinges formed to help in collapsing of the sleeve in a pre-determined manner and identification markings included as part of the living hinges.

Figure 24 is an enlarged drawing of a section of living hinges from Figure 23 showing how the identification markings can be formed of indentations.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS:

The protective sleeve disclosed in the Kuracina patent is shown as being a separate component mounted over the base of a needle attached to a hypodermic syringe. Figures 6-12 depict several modifications which can be made to the basic Kuracina protective sleeve and an associated hypodermic syringe.

Typically, in a prior art hypodermic syringe, the needle base is mounted over a cylindrical projection extending from the barrel. In the embodiment of this invention shown in Figures 6-12, there is a needle/sleeve assembly 30 having a cylindrical hub assembly 32 which is threaded into internal threads 34 of a cylindrical hub 36 extending from the barrel 12 of the syringe 10. The hub assembly 32 comprises a cylindrical outer hub 38 which has a cylindrical inner hub 40 disposed therein. For alignment purposes, where desired, the inner hub 40 is retained by the projections 42 fitting into the bores 44. Both the hubs 38, 40 are made of injection molded plastic and, therefore, they have a degree of flexibility which allows them to be snap-fit together. The inner hub 40 has ears 46 projecting outward therefrom which engage the threads 34 as the inner hub 40 is treaded into the outer hub 38. The inner hub 40 also concentrically holds the needle 16 at its base end in a bore 48 provided therefor. The outer hub 38 has the protective sleeve assembly 50 extending concentrically therefrom.

The protective sleeve assembly 50 comprises a cap-gripping hub 52 at the base end with the retracting slats 54 extending therefrom. The outer ends of the slats 54 are connected by an end cap 56. The preferred end cap 56 is configured as depicted in Figures 6 and 7. There is a central opening 58 which fits close to the needle 16 and back from the heel of the tip 18. A transparent bell end 60 extends outward from the central opening 58. Preferably, the bell end 60 is formed in a polished portion of the mold in which the protective sleeve assembly 50 is formed as a unitary structure so as to be

transparent and allow inspection of the bevel of the tip 18 without the necessity of retracting the protective sleeve assembly 50. The central opening 58 being located back from the heel of the tip 18 allows the protective sleeve assembly 50 to  
5 be retracted without the heel of the tip 18 contacting the material of the protective sleeve assembly 50. The closeness of the fit of the central opening 58 to the diameter of the needle 16 also tends to prevent foreign matter from entering the protective sleeve assembly 50 behind the tip 18.

10 Another improvement shown in Figures 6 and 7 is the shape of the front and rear retaining projections 62 and 64, respectively. Both are triangular in shape. It has been found in tested embodiments that the triangular shape allows for easier assembly and, at the same time, assures that the locking collar is  
15 held in its retracted position when "cocked" for use; yet, surely and quickly releases to return to the locked position when the slats 54 have been flexed in use and then unflex upon withdrawal of the needle 16.

Another important aspect of the present invention is the  
20 inclusion of the cap-retaining hub 52 at the bottom of the slats 54 adjacent the outer hub 38. The cap-retaining hub 52 comprises a disk portion 66 having a plurality of radial vanes 68 extending forward therefrom. The vanes 68 can be employed to screw and unscrew the inner hub 40 with respect to the  
25 cylindrical hub 36 extending from the barrel 12 of the syringe 10. The disk portion 66 and vanes 68 in combination can also support a hard cover 70 as shown ghosted in Figure 9. The hard cover 70 can include inner projections 72 which fit between and engage the vanes 68 so that the hard cover 70 can be used to  
30 screw and unscrew the inner hub 40 with respect to the cylindrical hub 36 in a fully protected manner. The hard cover 70 is also shown in a side, cutaway view in Figure 16. Note that the open end 88 is tapered inward to grip the disk portion 66 and vanes 68 as the hard cover 70 is pressed into place so as to

prevent its inadvertent loss prior to intended removal for use. Additional novel aspects of the hard cover 70 are addressed in another patent application entitled HARD COVER FOR PROTECTED INJECTION APPARATUS filed on even date  
5 herewith.

Additional modifications and improvements are shown in Figure 13. The Kuracina patent, of course, disclosed the addition of a spring-biased locking collar over the protective sheath as mentioned earlier herein. Several modifications for  
10 improved ease of assembly and operation can be made, however. For one, gripping tabs 74 can be provided at the inner ends of the vanes 68 to grip and retain the inner end of the spring 76. For another, the locking collar 78 can have an inner cylindrical portion 80 over which the spring 76 slides and  
15 unslides easily and which prevents the spring 76 from bunching and binding in any way. The locking collar 78 can also have an outer cylindrical portion 82 which covers and protects the front projections 62 from inadvertently being depressed so as to release the locking collar 78 and spring 76. Note at this point  
20 and with reference to Figure 13 that the previously mentioned triangular shape of the front projections 62 allows the locking collar 78 to slide over the front projections 62 and urge them inward during assembly. After the locking collar 78 has passed over the front projections 62 during assembly, they simply snap  
25 back into their normal retaining position as shown in Figure 13.

As mentioned in the foregoing description, if it is desired that the inner hub 40 and needle 16 have a particular alignment orientation with respect to the outer hub 38 and the protective sleeve assembly 50 carried thereby, the projections 42 which fit  
30 into the mating bores 44, or a like approach, can be employed. As those skilled in the art will readily recognize and appreciate, alignment of components increases the difficulty of assembly. If a definite alignment is not required, therefore, the approach of Figures 14 and 15 is preferred. In this case, the outer hub 38 is

provided with an inner peripheral groove 84 and the inner hub 40 is provided with an outer peripheral ridge 86 (continuous or discontinuous) which snaps into the groove 84 when the two hubs 38, 40 are pressed together in concentric alignment.

5 Longitudinal serrations can also be added to prevent twisting.

Turning now to Figures 17 and 18, a protective sleeve assembly 50' for use in dental applications, and the like, is shown. The protective sleeve assembly 50' has an extended unslit front portion 90 with the slats 54 only in the rear portion 92.

10 As best appreciated from Figure 18 this results in only a small portion of the needle 16 being exposed in the cocked or retracted position of the protective sleeve assembly 50', which is sufficient for dental work. More importantly, however, the outward expansion of the slats 54 takes place outside of the  
15 patient's mouth. This is more comfortable for the patient and more convenient for the dentist. The folded slats 54 can actually be employed to hold the protective sleeve assembly 50' in its retracted position and to guide the needle 16 into the desired positions for injection.

20 In certain uses, it is important to know the position of the bevel of the tip 18. In these instances and for such uses, the approach of Figures 19 and 20 can be employed to advantage. The inner hub 40 holding the inner end of the needle 16 is provided with an alignment projection 96 having a known  
25 orientation and relationship to the position of the bevel of the tip 18. The bore 94 in the outer hub 38 in which the inner hub 40 is disposed is provided with a mating alignment groove 98 which receives the alignment projection 96. Additionally, the  
30 bell end 60 (or some other convenient location) of the protective sleeve assembly 50 is provided with an indicia 100 (such as a bump as depicted in Figure 19) in known alignment with the bevel of the tip 18 after assembly of the above-described components. Thus, if assembled as depicted in Figures 19 and 20, a user knows that the bevel of the tip 18 is up

if the bump indicia 100 is up. It may also be found to be desirable to bevel the bottom of the bell end 60' backwards on the bottom as indicated at 61 in Figure 19 when using the needle 16 to perform certain intradermal and sub-cutaneous procedures.

As depicted in Figure 21, by reversing the position of the front projections 62' and adding a retaining ridge 102 adjacent the bell end 60, the protective sleeve assembly 50" can be made to be a one-time use apparatus. The protective sleeve assembly 10. 50" is shipped with the locking collar 78 in a pre-cocked state as shown ghosted in the drawing figure. This is permissible because it is only after use that needle-stick becomes a problem. Prior to use, accidental needle-stick may be painful, but typically that is all. After the pre-cocked syringe is used, the locking 15 collar 78 is released and moves forward to its extended and locked position as indicated by the arrow 104. Instead of being stopped by the front projections 62' in the normal manner, however, the locking collar 78 slides up the triangular ramp sides of the front projections 62' causing them to move inward 20 and allowing the locking collar 78 to pass over them. The locking collar 78 is then stopped in its forward movement by the retaining ridge 102. Because the vertical surface of the triangular front projections 62' is now behind it, the locking collar 78 cannot move towards its retracted position. It is thus 25 locked against further use and is good for only one use.

Two additional modifications for improved performance under certain conditions are depicted in Figure 22. A strong back 106 can be formed in the slats 54 extending backward from the front projections 62 to cause flexing of the slats 54 at a point 30 more removed from the bell end 60. This has been found to aid in the reliable and consistent operation of the protective sleeve assembly 50 in some cases and configurations. For uses such as subcutaneous and venous injection where it is important to be able to view the tip 18 of the needle 16 during placement and

insertion, the bell end 60 must be manually retracted to expose the tip 18. To facilitate such retraction, it is preferred that gripping ridges 107 be formed into the plastic of the end cap 56 of the protective sleeve assembly 50 extending outward behind  
5 and adjacent to the bell end 60 as depicted in Figure 22. The gripping ridges 107 allow the end cap 56 to be retracted easily and securely without interfering with the sterility of the needle tip, particularly if rubber gloves are not used.

Finally, it has been found that in certain cases and  
10 configurations additional consistency and reliability of performance can be attained by including so-called "living hinges" 108 at points of bending of the slats 54. As those skilled in the plastic arts are well aware, living hinges are places where the thickness of the plastic of an article is reduced. As with any  
15 material, it will bend at a line of reduced thickness. Because of the unique plastic and memory qualities of plastics, however, living hinges formed therein are self-biasing and not subject to fatigue and failure as in the case of metals. In addition, in a co-  
pending application entitled MEDICAL DEVICE  
20 ACCOUNTABILITY MARKING, TRACKING, AND DISPOSAL METHODS AND APPARATUS a method of marking individual medical devices to allow tracking and accountability thereof is disclosed. In the case of injection  
25 devices protected by a plastic protective sleeve assembly 50, the identification markings 110 can be incorporated into the living hinges 108 and, in fact, the living hinges 108 can be formed, at least in part, by making the identification markings 110 as a series of indentations 112 in the plastic of the protective sleeve assembly 50 at the locations of the living hinges 108.

30 Wherefore, having thus described the present invention, what is claimed is:



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1. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle, the improvement for minimizing the chance for damage to the injection end of the hypodermic needle comprising:

said outer end being bell-shaped with a point of sliding contact on the hypodermic needle located behind the injection end.

2. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 1 wherein:

said bell-shaped outer end of the hypodermic needle is transparent whereby the injection end of the hypodermic needle can be visually inspected through said bell-shaped outer end.

3. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle is carried by a medical device employing the hypodermic needle, the improvement for making the hypodermic needle attachable to and releasable from the medical device comprising:

a) a projection extending from the medical device; and,  
b) attachment means included with the base for releasably attaching the hypodermic needle in combination with the retractable sleeve to said projection.

4. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 3 wherein:

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- a) said projection is a cylindrical projection having a cylindrical bore therein; and,
- b) said attachment means comprises a cylindrical member sized and shaped to slidably fit within said cylindrical bore.

5        5. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 4 wherein:

- a) said cylindrical bore has internal threads  
10   formed therein; and,
- b) said cylindrical member has external projections which threadedly engage said internal threads whereby said cylindrical member is threaded into said cylindrical bore to releasably attach the hypodermic needle in combination  
15   with the retractable sleeve to said projection.

6. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 3 wherein:

- a) the base includes radial longitudinal gripping  
20   vanes; and additionally comprising,
- b) a hard cover disposed over the retractable sleeve and supported by said vanes, said hard cover having interacting means on an inner surface thereof for radially pushing said vanes to release said attachment means from said  
25   projection when said hard cover is rotated whereby said hard cover can be used to attach the hypodermic needle and the retractable sleeve in combination therewith to said projection and release the hypodermic needle and the retractable sleeve in combination therewith from said projection.

30

7. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the

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hypodermic needle is carried by a medical device employing the hypodermic needle, the improvement for making the position of the injection end of the hypodermic needle determinable while still covered by the retractable sleeve comprising:

5                   a) a projection extending from the medical device; and,

                  b) attachment means included with the base for releasably attaching the hypodermic needle in combination with the retractable sleeve to said projection; wherein,

10                  c) the base comprises a first part carrying the bottom end of the hypodermic needle and a second part carrying bottom ends of the plurality of longitudinal slats; and additionally,

                  d) the base includes means for placing the  
15 injection end of the hypodermic needle in a pre-determined positional orientation with respect to the retractable sleeve.

8. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 7 wherein:

20                  said means for placing the injection end of the hypodermic needle in a pre-determined positional orientation with respect to the retractable sleeve comprises said first part and said second part being parts of a unitary structure comprising the base with the injection end of the hypodermic  
25 needle carried thereby in said pre-determined positional orientation with respect to the retractable sleeve.

9. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 7 wherein:

30                  said means for placing the injection end of the hypodermic needle in a pre-determined positional orientation with respect to the retractable sleeve comprises mating portions of said first part and said second part which only mate when the

injection end of the hypodermic needle is in said pre-determined positional orientation with respect to the retractable sleeve.

10. The improvement to a hypodermic needle disposed  
5 within a retractable sleeve of claim 7 and additionally comprising:

indicia means carried by the retractable sleeve for indicating to a user said pre-determined positional orientation of the injection end of the hypodermic needle with respect to  
10 the retractable sleeve whereby a user can place the injection end of the hypodermic needle in a desired positional orientation before retracting the retractable sleeve.

11. The improvement to a hypodermic needle disposed  
15 within a retractable sleeve of claim 10 wherein the retractable sleeve has a bell end covering the injection end of the hypodermic needle and additionally comprising:

a bottom portion of said bell end being beveled backwards whereby the hypodermic needle is more easily used  
20 for intradermal and sub-cutaneous procedures.

12. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle  
25 and an outer end slidably covering an injection end of the hypodermic needle wherein a sliding collar and bias spring are disposed over the retractable sleeve with the spring disposed between the base and the sliding collar to bias the sliding collar towards the outer end, the improvement for preventing  
30 undesired movement of the spring comprising:

gripping tab means carried by the base for gripping and holding a base end of the spring.

13. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle wherein a sliding collar and bias spring are disposed over the retractable sleeve with the spring disposed between the base and the sliding collar to bias the sliding collar towards the outer end and the slats have front and rear projections extending therefrom to prevent the sliding collar from sliding off the outer end and to releasably latch the sliding collar in a retracted position for use, the improvement for increasing the reliability of operation comprising:

the projections being triangles in shape having a vertical side adjacent the base and a sloped side facing the outer end.

14. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 13 wherein additionally:

the sliding collar has an extended inner cylindrical portion which fits under a plurality of turns of the spring when the sliding collar is moved to a retracted position behind rear ones of the projections.

15. The improvement to a hypodermic needle disposed within a retractable sleeve of claim 13 wherein additionally:

the sliding collar has an extended outer cylindrical portion which covers and protects front ones of the projections from unwanted depression and release of the sliding collar when the sliding collar is in an extended position held by said front ones of the projections.

16. In a hypodermic needle disposed within a retractable sleeve extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an

injection end of the hypodermic needle wherein the retractable sleeve includes a portion containing a plurality of longitudinal folding slats formed by a plurality of longitudinal slots in the retractable sleeve, the improvement for dental use and the like comprising:

the plurality of longitudinal slots being located longitudinally offset more adjacent the base than the outer end whereby the plurality of longitudinal folding slats fold adjacent the base and an extended portion of the retractable sleeve adjacent an exposed injection end of the hypodermic needle is not deformed outward during retraction of the outer end.

17. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle wherein a sliding collar and bias spring are disposed over the retractable sleeve with the spring disposed between the base and the sliding collar to bias the sliding collar towards the outer end and the slats have front and rear projections extending therefrom to control movement of the sliding collar, the improvement to make the hypodermic needle usable only once comprising:

a) the projections being triangles in shape with rear ones of the projections having a vertical side adjacent the base and a sloped side facing the outer end and front ones of the projections having a sloped side adjacent the base and a vertical side facing the outer end; and,

b) retaining ridge means for not allowing the sliding collar to pass thereover disposed adjacent the outer end and past said front ones of the projections towards the outer end whereby the locking collar when released from a retracted position held by said rear ones of the projections is moved over said front ones of the projections by a biasing force of the spring

and locked between said front ones of the projections and said retaining ridge means.

18. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle wherein a sliding collar and bias spring are disposed over the retractable sleeve with the spring disposed between the base and the sliding collar to bias the sliding collar towards the outer end and the slats have front and rear projections extending therefrom to prevent the sliding collar from sliding off the outer end and to releasably latch the sliding collar in a retracted position for use, the improvement for increasing the reliability of operation comprising:

thickened strongback areas in the plurality of longitudinal slats extending from respective ones of the front projections toward the base.

19. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle wherein a sliding collar and bias spring are disposed over the retractable sleeve with the spring disposed between the base and the sliding collar to bias the sliding collar towards the outer end and the slats have front and rear projections extending therefrom to prevent the sliding collar from sliding off the outer end and to releasably latch the sliding collar in a retracted position for use, the improvement for increasing the ease of manual retraction of the retractable sleeve comprising:

a gripping area extending radially outward from the outer end, said gripping area having a high friction surface

whereby a user can reliably grip and pull the outer end longitudinally toward the base even when the outer end is covered with slippery fluid.

- 5        20. In a hypodermic needle disposed within a retractable sleeve comprised of a plurality of longitudinal slats extending between a base carrying a bottom end of the hypodermic needle and an outer end slidably covering an injection end of the hypodermic needle, the improvement for increasing the  
10 · reliability of operation comprising:  
              respective ones of the plurality of longitudinal slats having transverse areas forming living hinges at corresponding locations of intended bending.



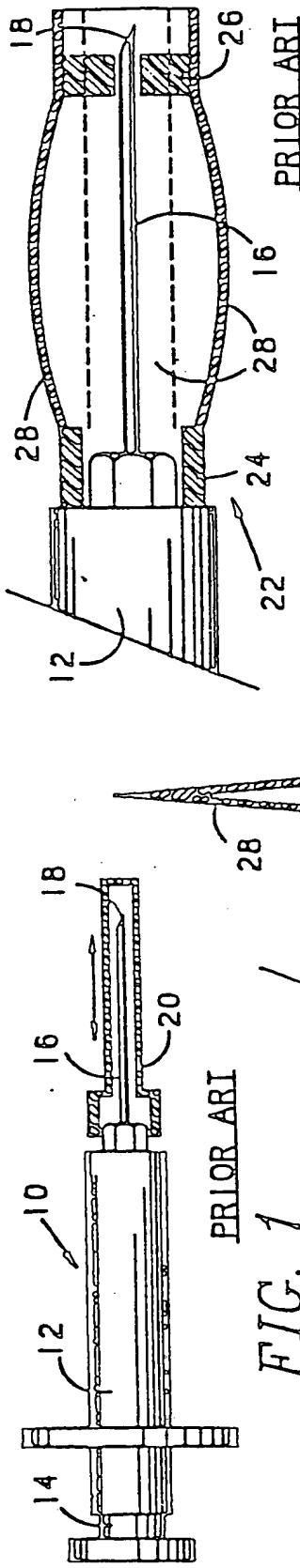
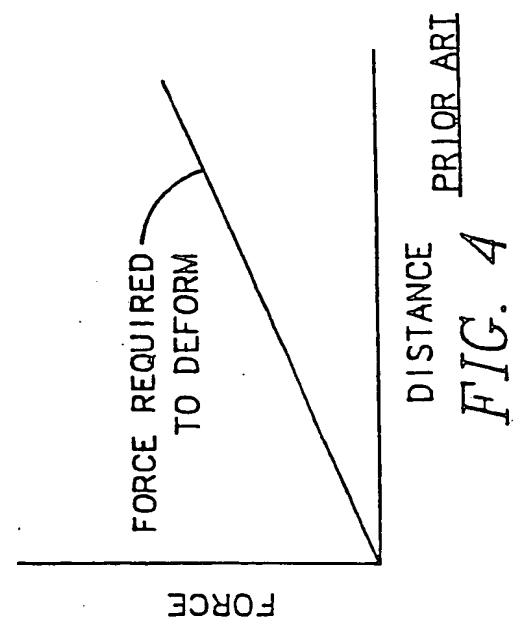
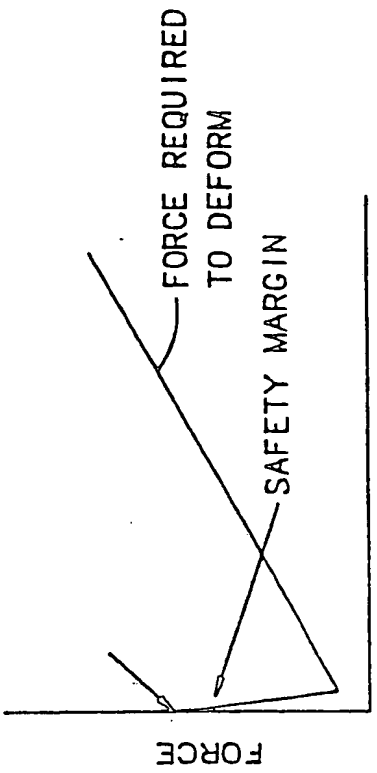
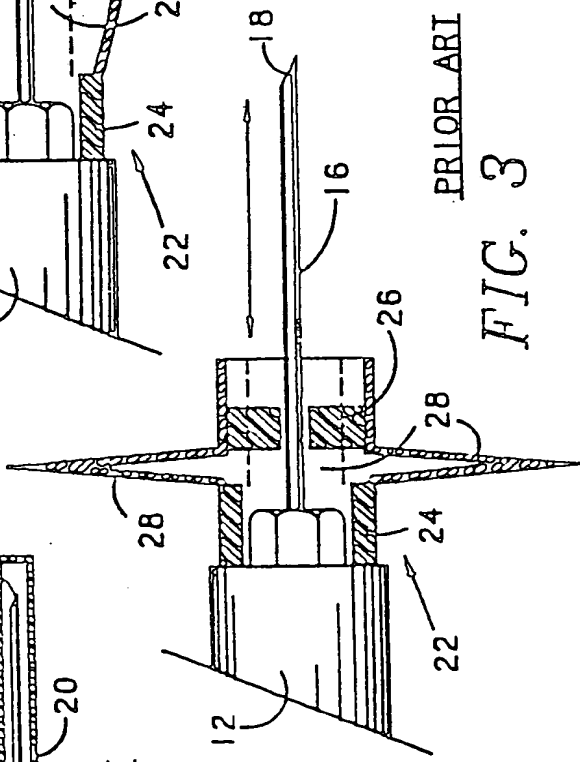
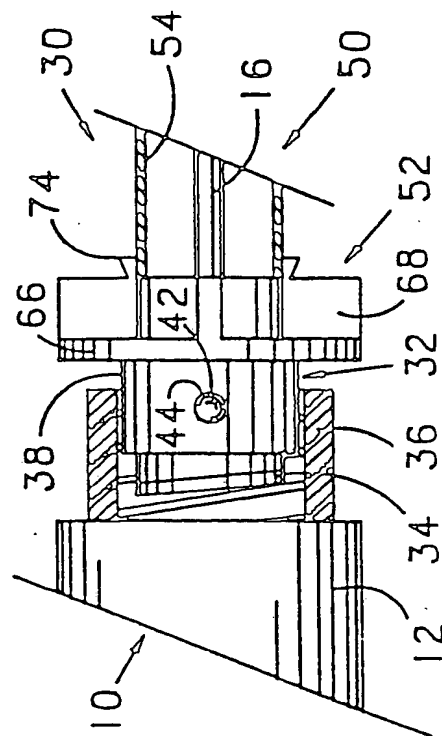
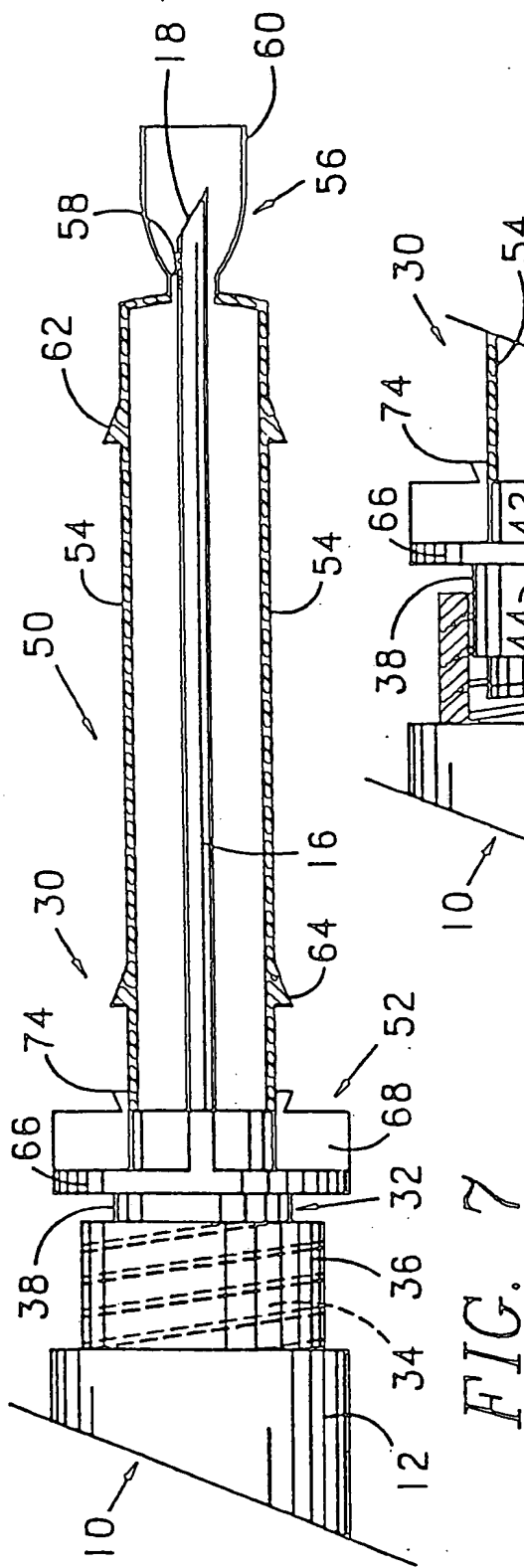
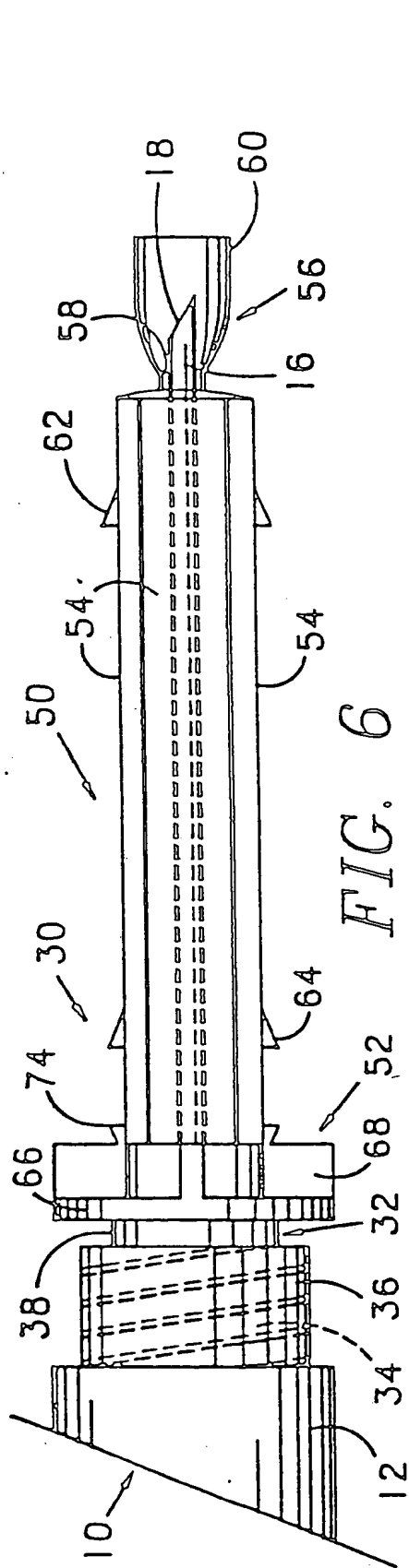


FIG. 2



FIG. 3





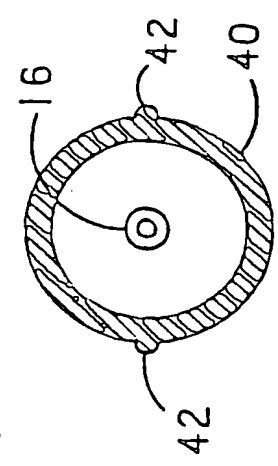
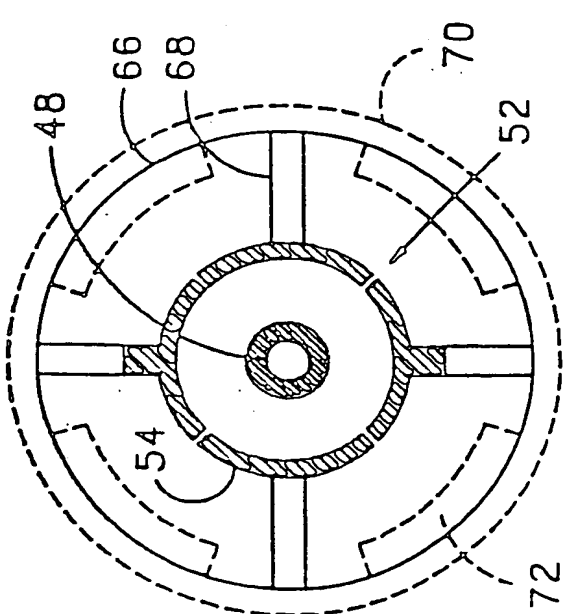
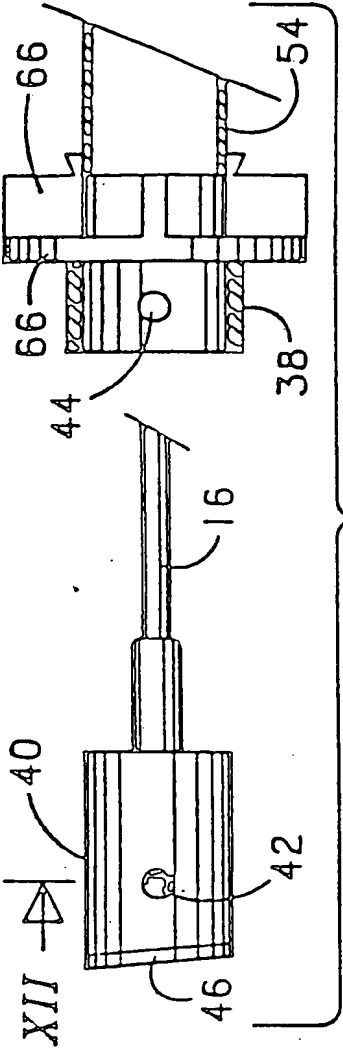
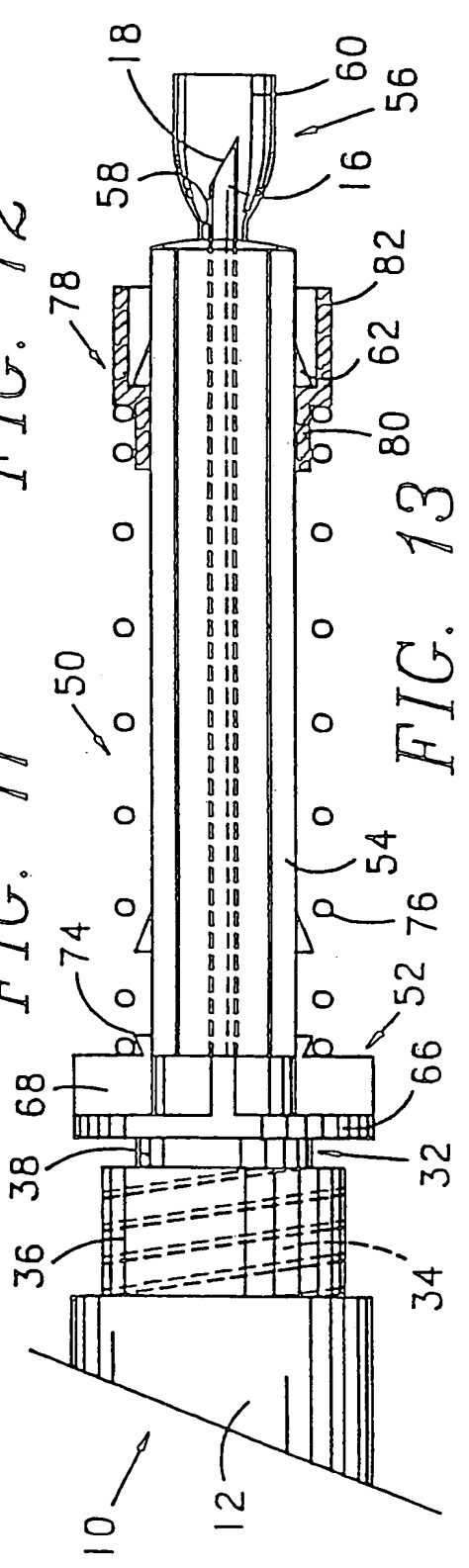


FIG. 12

FIG. 13



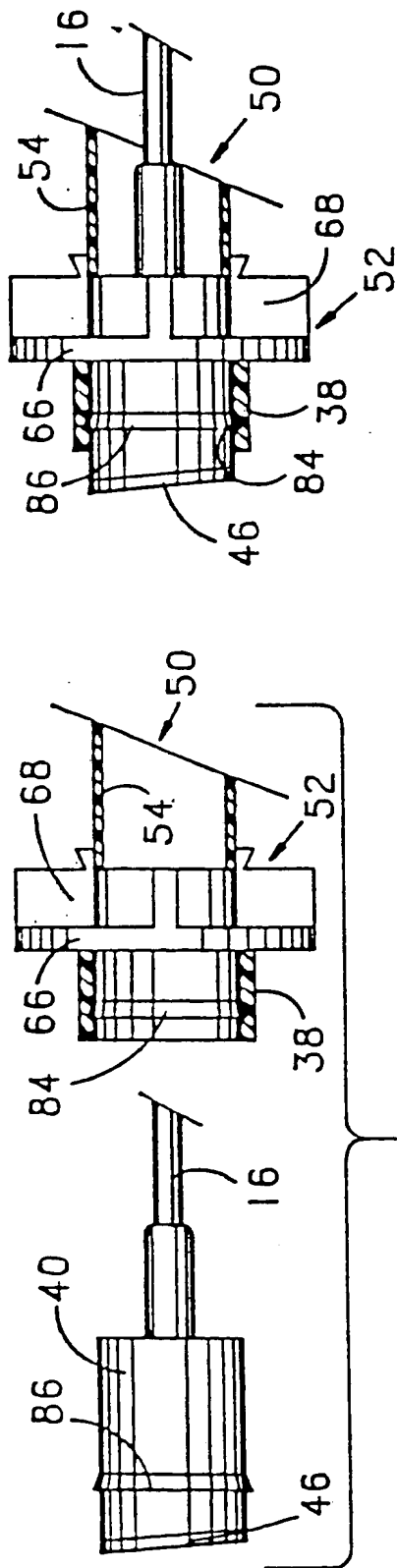


FIG. 15

FIG. 14

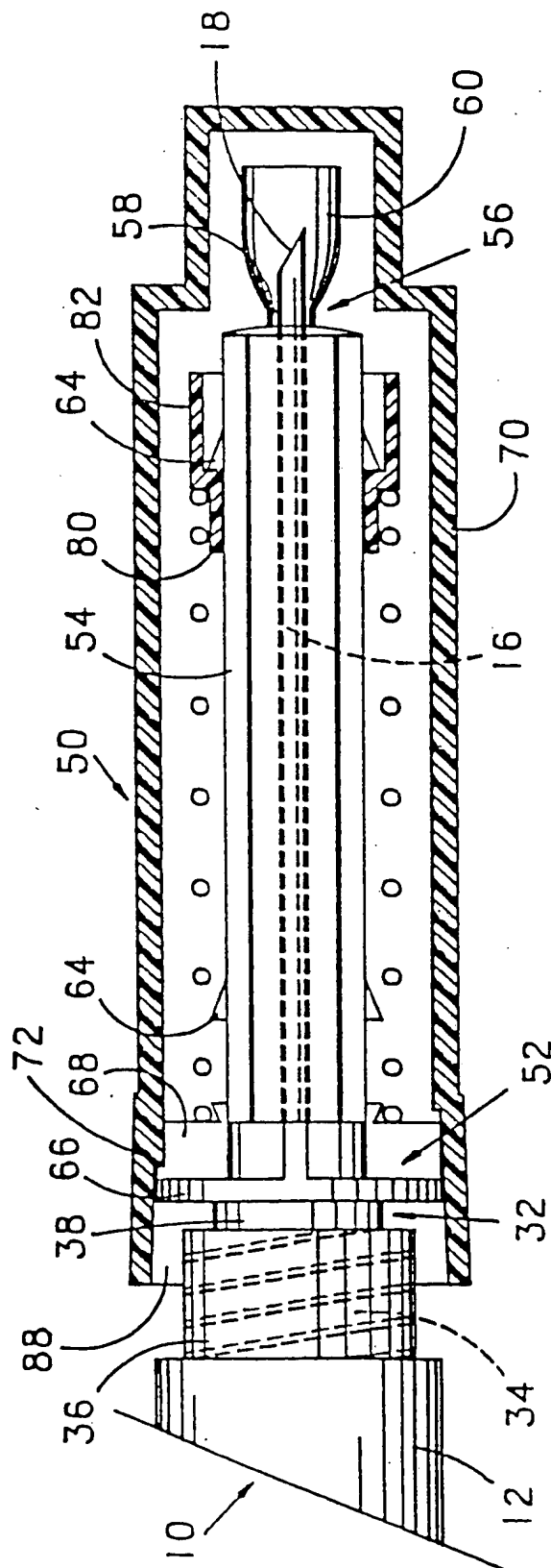
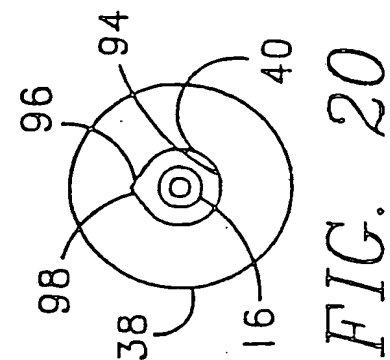
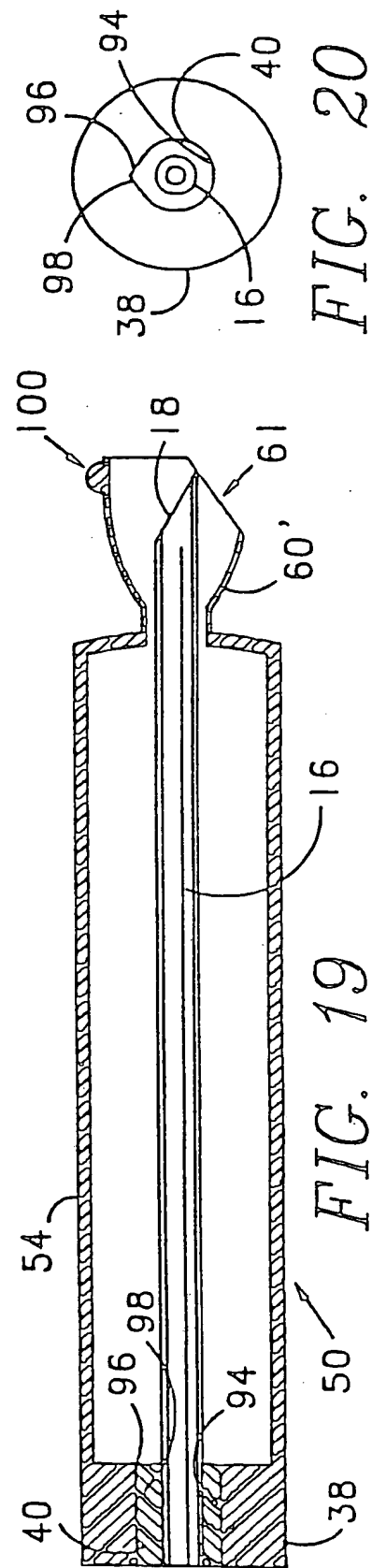
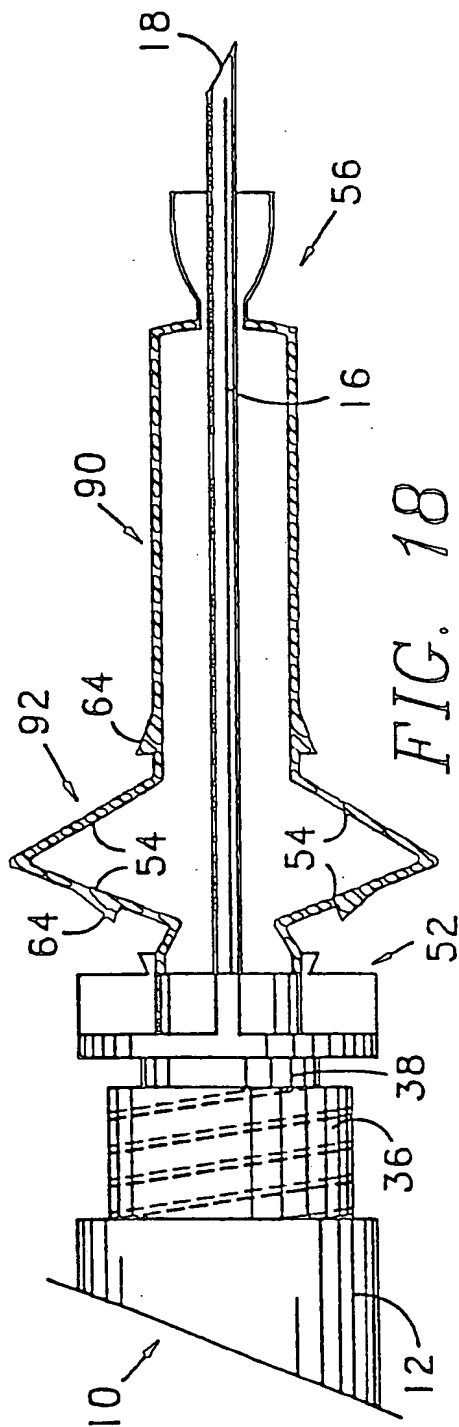
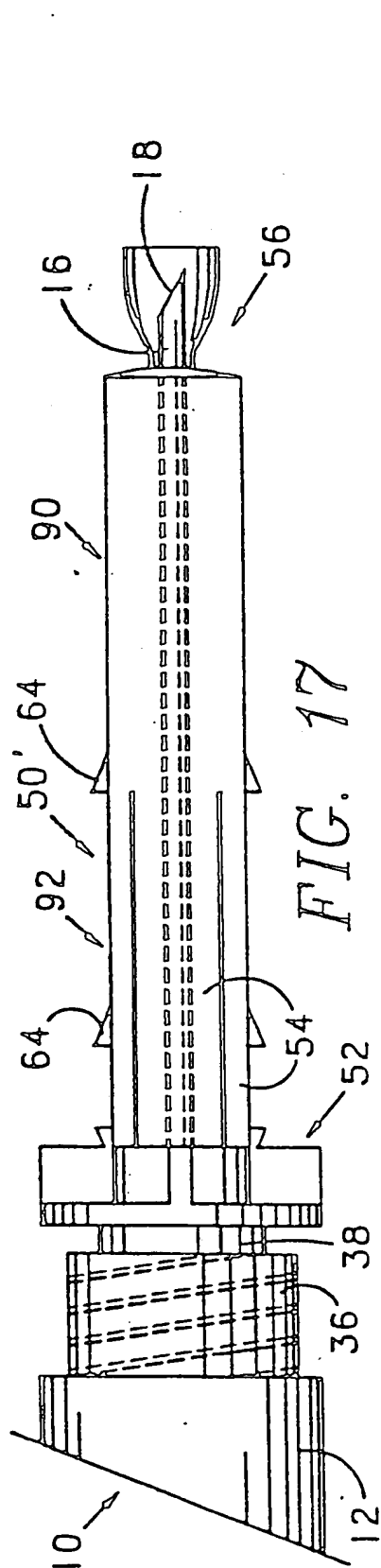
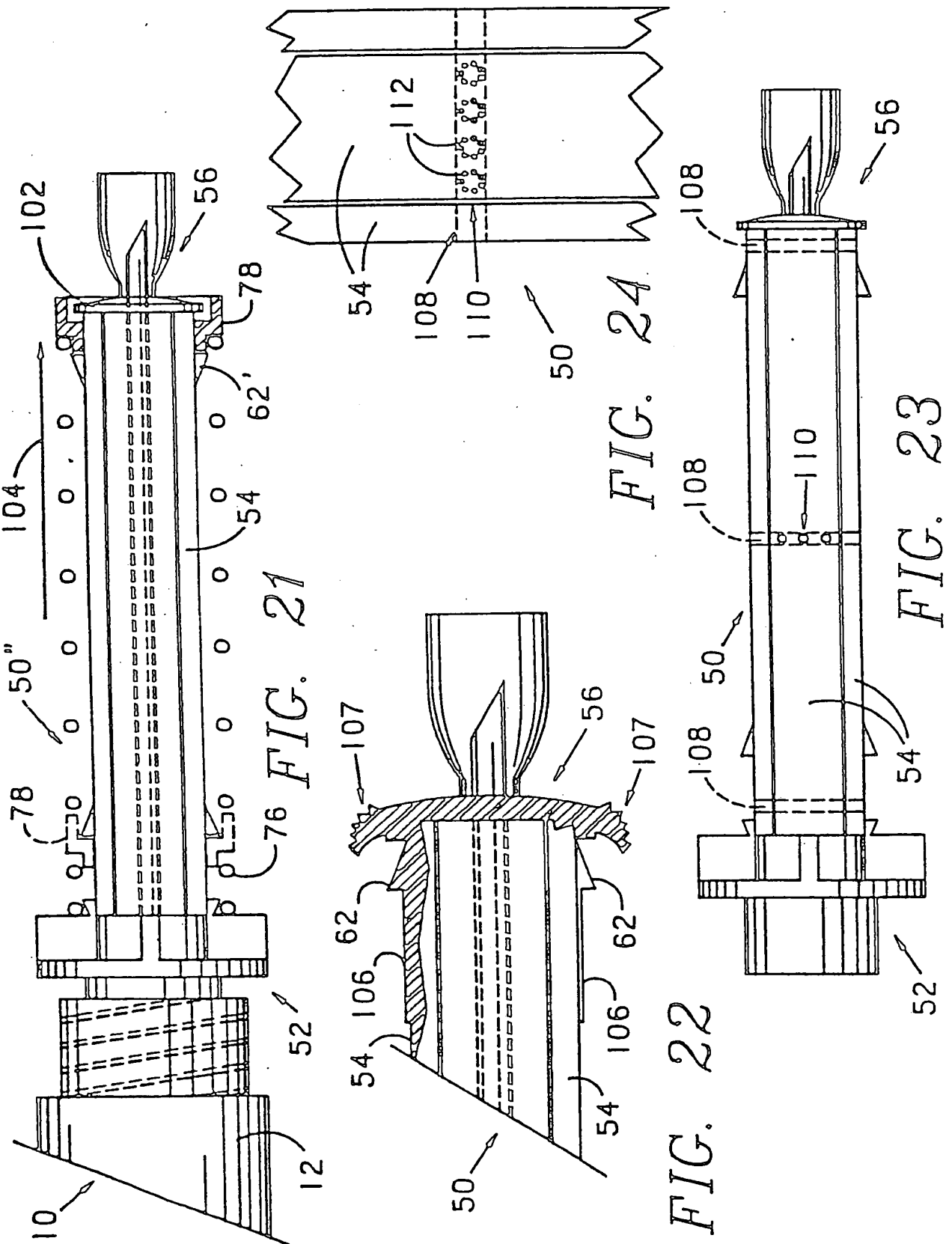


FIG. 16







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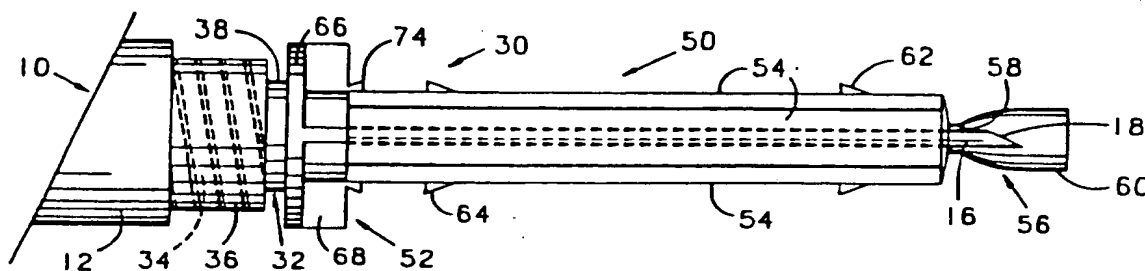
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## (57) Abstract

Improvements to hypodermic needle (16) disposed within a retractable sleeve (50) comprised of a plurality of longitudinal slats (54) extending between a base (40) carrying the needle (16) and an outer end (60) covering the needle's tip (18). There is a releasable base (40) attaching to a device such as a syringe (10). The base (40) supports a hard cover (70) used to attach and release the needle (16) and sleeve (50). A bell end (60) provides a point of sliding on the needle (16) behind the tip (18) and viewing of the tip (18) when transparent. The tip (18) is placed in a pre-established orientation and the sleeve (50) is marked so that the needle (16) can be positioned before the sleeve (50) is retracted. Where a spring-biased collar (78) is used over the sleeve (50), the base (40) has gripping tabs (74) to hold the spring (76), the collar (78) has an extended area for sliding stacking of the spring (76) upon retraction, and another extended area for protecting the front holding projections (62) when the sleeve (50) is extended.

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## INTERNATIONAL SEARCH REPORT

 International application No.  
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## A. CLASSIFICATION OF SUBJECT MATTER

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US CL : 604/189, 192

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US, A, 4,760,847 (VAILLANCOURT) 02 August 1988, See figures 1,2,4 and 5.	10
X	US, A, 4,887,998 (MARTIN ET AL.) 19 December 1989, See figures 4 and 5.	3,4,5,6
X --- Y	US, A, 4,898,589 (DOLGIN ET AL.) 06 February 1990, See entire document.	3-5,7-9,16, 18,20 ----- 10
X	US, A, 4,911,693 (PARIS) 27 March 1990, See entire document.	3,4,5,12
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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US, A, 4,998,922 (KURACINA ET AL.) 12 March 1991, See entire document.	13-15,17, 18,20
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X	US, A, 4,935,013 (HABER ET AL.) 19 June 1990, See entire document.	3-5,7-9,18, 20
X	US, A, 4,790,828 (DOMBROWSKI ET AL.) 13 December 1988, See entire document.	3-9,16,18, 20
X	US, A, 5,078,697 (RAMMLER) 07 January 1992, See entire document.	18,20
X,P	US, A, 5,120,309 (WATTS) 09 June 1992, See entire document.	1,2
---		---
Y		10,11
Y	US, A, 4,976,699 (GOLD) 11 December 1990, See figure 1a.	11
A	US, A, 4,139,009 (ALVAREZ) 13 February 1979, See entire document.	NONE
A	US, A, 4,735,618 (HAGEN) 05 April 1988, See figures 1 and 2.	NONE
A	US, A, 4,867,172 (HABER ET AL.) 19 September 1989, See entire document.	NONE
A	US, A, 5,069,669 (KOLE) 03 December 1991, See entire document.	NONE
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